119

Guidance for Industry and Reviewers

How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug

Draft Guidance

Distributed for Comment Purposes Only

This guidance announces the Center for Veterinary Medicine's (CVM's) policy regarding the circumstances under which CVM intends to discontinue review of submissions filed during the investigation of a new animal drug, notify the sponsor that review has been discontinued, and remove the submission from the queue.

Comments and suggestions regarding this document should be sent to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fisher's Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. found at the top of the Federal Register notice which announces the availability of this guidance.

For questions regarding this draft document, contact Gail L. Schmerfeld, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-0205, E-mail: gschmer1@cvm.fda.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
March 23, 2001

Guidance for Industry and Reviewers

How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug

This guidance represents the Agency's current thinking on the circumstances under which CVM intends to discontinue review of submissions filed during the investigation of a new animal drug, notify the sponsor that review has been discontinued, and remove the submission from the queue. This guidance does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Introduction:

CVM's Office of New Animal Drug Evaluation (ONADE) encourages sponsors to submit data, protocols, or other information for review at the most appropriate and productive times in the drug development process rather than submitting all data at one time in a New Animal Drug Application (NADA). Thus, sponsors may submit data intended to support an application for new animal drug approval during the investigation of the new animal drug to an investigational new animal drug (INAD) file. This guidance announces CVM's policy regarding the circumstances under which ONADE intends to discontinue review of the sponsor's submission relating to a new animal drug approval (filed to the INAD file), notify the sponsor that review has been discontinued, and remove the submission from the queue.

ONADE currently has a significant backlog in the number of submissions pending review. This has prompted ONADE to look at its review process. ONADE found that one of the significant inefficient uses of reviewer resources is the number of submissions received by ONADE that require significant additional information or rehabilitation in order for ONADE to complete its review. ONADE's practice has been to keep a submission "active" pending the submission of additional information from sponsors.

Instead of keeping deficient submissions "active" pending the submission of additional or revised information, ONADE intends to handle them under the policy set out in this guidance. If ONADE finds minor deficiencies, ONADE should request an amendment. But, if ONADE finds that a submission is significantly deficient, ONADE should notify the sponsor that it intends to discontinue review of the submission and remove it from the queue. This policy will permit ONADE to focus on reviewing quality submissions that contain all the information necessary for ONADE to evaluate the submission, thereby facilitating new animal drug approvals.

Notifying a sponsor that ONADE intends to discontinue review of a submission and remove it from the queue

When a review Division receives a submission, the Consumer Safety Officer, reviewer, or Team Leader should make a cursory review of the submission to ensure that the submission is complete on its face. If the submission appears to be incomplete, the person making the appraisal, in concert with the Division Director, should make the decision whether to request an amendment or to notify the sponsor that ONADE intends to discontinue reviewing the submission and to remove it from the queue. If ONADE finds only minor deficiencies, the Division should request an amendment. If the person making the appraisal finds significant deficiencies[1] that would prevent ONADE from reasonably evaluating the submission, the Division should notify the sponsor by letter.

Similarly, if, after a reviewer begins the review of a submission, the reviewer finds that the number or type of errors in a submission or flaws in the development plan cause the reviewer and Team Leader to (1) conclude that the submission cannot reasonably be reviewed or (2) question the quality of the entire submission,[2] the Division should notify the sponsor by letter. The decision to discontinue review of a submission and remove it from the queue should be made by the reviewer and Team Leader with concurrence from the Division Director.

The letter to the sponsor should (1) state that the review of the submission has been discontinued, (2) summarize in general terms the reasons that review of the submission has been discontinued, and (3) inform the sponsor that the submission has been removed from the queue. The letter should also remind the sponsor that the sponsor may request a meeting with ONADE to discuss why review of a submission was discontinued and how best to proceed with drug development and submission of data. Finally, the letter should inform the sponsor that any resubmission of data or information should go through a thorough review process by the sponsor before it is resubmitted to make sure that all the information is both accurate and complete.

NOTE: ONADE will continue to handle review of complete or supplemental NADA's in accordance with existing regulations set forth at 21 CFR Part 514. ONADE will make decisions on whether to refuse to file an application in accordance with 21 CFR 514.110 or will make its decision to approve or not approve an application based on the data submitted.

[1]Examples of significant deficiencies include missing data sets, missing components in the submission, and lack of detail in a study protocol.

[2] Examples of these types of errors could include discrepancies between electronic data sets and the paper copy, conflicting information between sections of the submission, and the absence of important information.